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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,923	01/14/2004	David W. Heeke	HDW102C	5124
32299	7590	10/27/2006		
DENISE M GLASSMEYER YOUNG & BASILE, P.C. 3001 W. BIG BEAVER RD., SUITE 624 TROY, MI 48084-2813			EXAMINER DIXON, ANNETTE FREDRICKA	
			ART UNIT	PAPER NUMBER
			3771	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,923

Applicant(s)

HEEKE ET AL.

Examiner

Annette F. Dixon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/14/2004.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION***Oath/Declaration***

1. The oath and declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67 (a) identifying this application-by-application number and filing date is required. MPEP §602.01 and §602.02.

The declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. Please see 37 CFR 1.52 (c).

2. In the specification of the current Application, Applicant discloses priority to a divisional application (10/172,315) and to a provisional application (60/298,997). In the oath and declaration, Applicant has listed the provisional application, but has not listed the divisional application. As such, Applicant's claim of priority requires correction and must be noted on the oath and declaration.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because the listed reference characters have been used to designate multiple elements.

Reference #	Element Name
10	Device Air Directing Element
14	Lower central plate member Lower member

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14 & 16	Connection means
50 & 52	Central plate
52 & 54	Upper face
54	Ridges Upper face
30	Bridges Upper plate

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

17, 19, 44, 84, 85, 87, 94, 120, 122, 124, 126, and 218

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "32" and "36".

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37

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CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: Examiner requires the Applicant to update the "cross reference to related application" section. Appropriate correction is required.

Claim Objections

8. Claim 1 is objected to because of the following informalities: Examiner suggests "removably insertable" as opposed to "removable insertable". Further, the word "and" is needed between the paragraphs containing the particulars of the "upper member" and the "lower member". Appropriate correction is required.

9. Claim 3 is objected to because of the following informalities: "the super bulge" lacks antecedent basis.

10. Claim 4 is objected to because of the following informalities: "the flexible shell" lacks antecedent basis.

11. Claim 8 is objected to because of the following informalities: "the super bulge" lacks antecedent basis.

Claim Rejections - 35 USC § 112

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12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 2 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP §608.04.

As to Claim 2, and its dependent claim 5, Claim 2 recites the "lower member is in permanent contact with the upper member." However, in Applicant's specification in paragraph 0083, Applicant discloses the "connection member 230 can be affixed in a semi-permanent or movable means". The aforementioned recitation does not include the "permanent" affixation of the lower member to the upper member. Because of this, Applicants recitation of "permanent" affixation is considered new matter and thus must be cancelled from the claims.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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15. Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Heeke et al. (5,562,106).

As to Claim 1, Heeke discloses an oral device removably insertable in the mouth of a user for facilitating breathing while sleeping comprising: an upper member (12), the upper member having upper and lower depressions and right and left sides corresponding to the location of at least back molars and second bicuspid configured to fit a mouth of a user (Column 5, Lines 4-8), said upper and lower depressions forming right and left biting surfaces wherein said biting surfaces are spaced at a height to force the mouth open the upper member further having a plate-like bridge (20) conforming to the back of the maxillary anterior and the upper plate of the mouth said bridge joining the biting surfaces; and a lower member (14) positioned in underlying spaced relationship relative to the plate-like bridge of the upper member, the lower member having a lateral member, the lateral member having an upper surface oriented toward the plate-like bridge, a lower surface opposed to the upper surface, and at least one curvilinear side surface extending from a frontal location to a terminal location proximate to the maxillary anterior of the user's mouth, the at least one side edge adapted to engage associated interiorly oriented regions of the upper member, the lower member positioned relative to the upper member so as to form an air passage for conveying introduced auxiliary pressured air from the mouth opening to the anterior of the mouth of the user. (Exhibit A). Regarding the curvilinear side surface limitation, inherently for a device to be placed inside the mouth and engaging the teeth the device must have an arcuate shape.

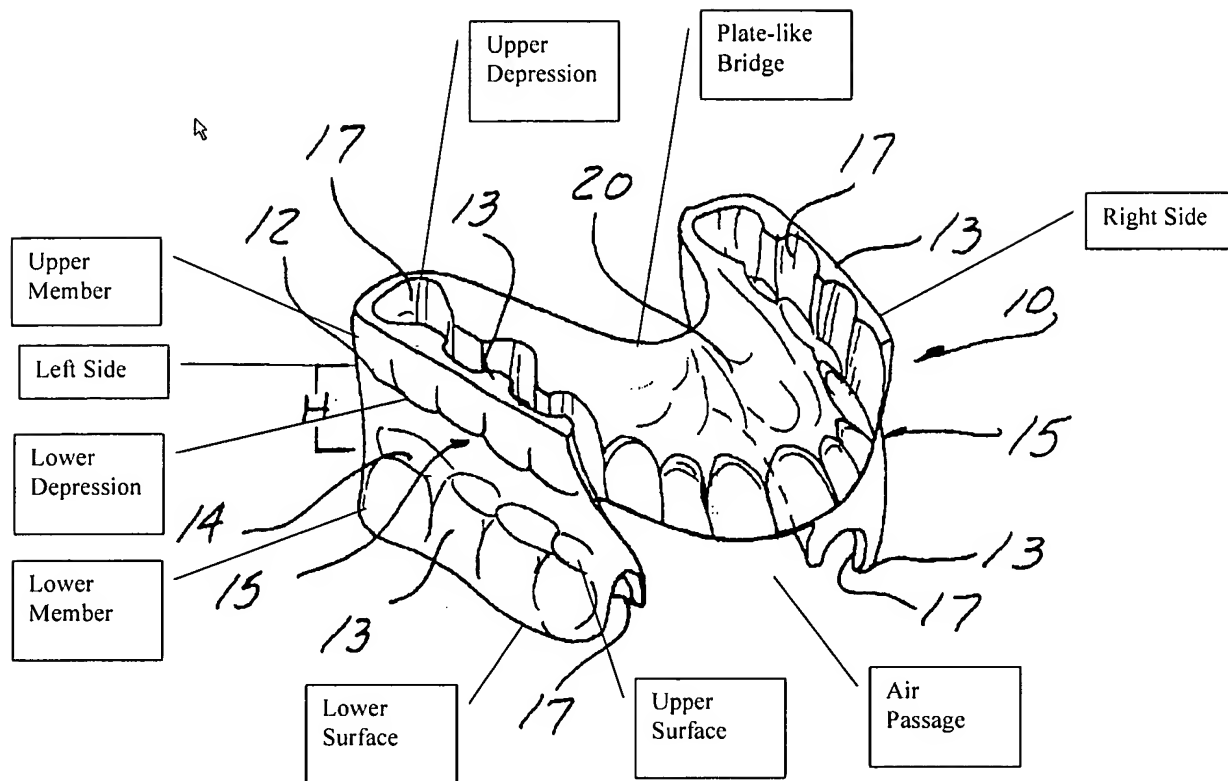


Exhibit A: Figure 1, Courtesy of Heeke et al. (5,562,106).

As to Claim 2, Heeke disclose a device wherein the lower member is in permanent contact with the upper member. (Figure 1).

As to Claim 3, Heeke discloses the upper member has a retentive portions extending over a super bulge of each of the back molars and second bicuspid. (Figure 1).

As to Claim 4, Heeke discloses a flexible shell, which extends over the gum line of the user having an edentulous mouth. (Column 5, Lines 4-8).

As to Claim 5, Heeke discloses a device wherein the plate-like bridge (20) conforms to the back of the maxillary anteriors and the upper palate of the mouth, said bridge joining the biting surfaces (Figure 1).

As to Claim 8, Heeke disclose the upper member comprises a plurality of tooth engaging regions, the tooth engaging regions including retentive portions extending over a super bulge of each of the associated back molars and second bicuspid of the user and tooth-contacting regions positioned proximate to frontal regions of the device, the frontal tooth contacting regions adapted to releasably contact at least a portion of the inner surfaces of upper front of the user. Regarding this limitation, as Applicant has only claimed the engagement with the bicuspid, the Examiner views the bicuspid to be a frontal tooth, as Applicant has not claimed the engagement of the central incisors, lateral incisors, or the cuspid, which have a more frontal orientation as opposed to the bicuspid.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 6, 7, 9-12, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heeke et al. (5,562,106) in view of Bradley et al. (5,626,128).

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As to Claims 6 and 7, Heeke discloses an oral device having an airway (Exhibit A) but does not expressly disclose the oral device to have a means for releasably connecting the airway with pressurized air and the air direction member to be integrally formed with the upper or lower members. However, at the time the invention was made the use of a mouthpiece having the ability to be engaged with a source of pressurized air. Specifically Bradley teaches an oral device having an endotracheal tube (14) attached via clips (the combination of elements 40 and 44) to enable the oral device to maintain the airway of the patient and provide respiratory assistance. (Background). Further, the air is directed under the plate region (22) to the patient. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Heeke to include an integrally formed airway to provide respiratory assistance to the patient.

As to Claim 9, Heeke discloses an oral device but does not expressly disclose a frontal shield for engaging the front teeth of the user. However, at the time the invention was made the use of a frontal shield for engaging the front teeth of the user was well known. Specifically, Bradley teaches an oral device having an endotracheal tube (14) and a frontal shield for engaging the front teeth of the user to enable the oral device to maintain the airway of the patient, to provide respiratory assistance, and to assist in the engagement of the device to the front teeth. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Heeke to include a front shield to assist in the engagement of the device to the front teeth.

As to Claim 10, the system of Heeke as modified by Bradley discloses a tooth-engaging region that engages at least the incisor located in the mandible of the user.

As to Claim 11, the system of Heeke as modified by Bradley discloses the connection of the pressurized air source to the lower member of the device.

As to Claim 12, the system of Heeke as modified by Bradley discloses a frontal shield, which communicates with the source of pressurized air and is in communication with the air channel formed by the upper and lower members.

As to Claim 15, the elements of claim 15 have been discussed in claim 1 with the exception of the means for releasably connecting the airway defined between the upper and lower members to a source of pressurized air external to the oral device. However, applicant is directed to the rejection of claim 6 using the prior art of Heeke in view of Bradley, which address this limitation.

As to Claims 16 and 17, as discussed in claim 15, the system of Heeke as modified by Bradley teaches a frontal shield used in combination with the air connection means. Applicant is directed to the rejection of claims 9 and 11.

18. Claim 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heeke et al. (5,562,106) in view of Kittelsen et al (6,675,807).

As to Claim 13, Heeke discloses an oral device but does not expressly disclose a means for connecting the upper and the lower members in a releasably essentially airtight manner. However, from a close reading of Applicant's specification, paragraph 0083, Applicant has not asserted criticality as to whether the device is affixed in a

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permanent or movable orientation. Nevertheless, at the time the invention was made the use of multiple pieces forming an upper and lower members capable of being engaged and disengaged was well known. Specifically, Kittelsen discloses an oral device has releasably detachable parts to aid in the customization and sterilization of the device (Background). Therefore, it would have been obvious to one having ordinary skill in the art to provide a means for the upper and lower members to be detachably engaged to enable sterilization of the device. Furthermore, Applicant has not asserted that the specific releasable engagement of the upper and lower members recited provides a particular advantage, solves a stated problem or serves a purpose different from that of encouraging the sterilization and customization of the device, thus the use of the releasably engaged device lacks criticality in its design.

As to Claim 14, as discussed in claim 13, the system of Heeke as modified by Kittelsen includes connecting means that clip the portions of the oral device.

19. Claim 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heeke et al. (5,562,106) Bradley et al. (5,626,128), and further in view of Kittelsen et al (6,675,807).

As to Claim 18, the system of Heeke as modified by Bradley is discussed above but does not teach the attachment means of an annular groove and at least two clips to enable the connection between the upper and lower members. However, at the time the invention was made, the attachment means of an annular groove on the upper member and the clip attachment means on the lower member were known. Specifically,

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Kittelsen discloses an oral device having releasably detachable parts and attachment means (the attachments of elements 110 to 116) to aid in the customization and sterilization of the device (Background). Therefore, it would have been obvious to one having ordinary skill in the art to provide a means for the upper and lower members to be detachably engaged attachment means to enable sterilization of the device.

Furthermore, Applicant has not asserted that the specific releasable engagement of the upper and lower members recited provides a particular advantage, solves a stated problem or serves a purpose different from that of encouraging the sterilization and customization of the device, thus the use of the releasably engaged device lacks criticality in its design.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Annette F Dixon
Examiner
Art Unit 3771
October 25, 2006



Danton D. DeMille
Primary Examiner